IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Hansen et al. Confirmation No. 2513

Application No.: 10/674,205 Group Art Unit: 3686

Filed: September 29, 2003 Examiner: Raj, Rajiv J.

For: Indicating Device With Estimating Feature

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Commissioner for Patents
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Appeal is from the Examiner's Final Rejection of claim 1 set forth in the Final Office Action mailed from the U.S. Patent and Trademark Office on September 22, 2008.

A Notice of Appeal in response to the Final Office Action was filed on December 19, 2008.

Payment in the amount of $ 540.00 is concurrently submitted as payment of the requisite fee under 37 C.F.R. § 41.20(b)(2), and payment in the amount of $1,110.00 is concurrently submitted as payment for the 3 month Extension of Time extending the time period for filing the Appeal Brief from February 19, 2009 to May 19, 2009. No additional fee is believed to be required for filing the instant Appeal Brief. However, if for any reason a necessary fee is required for consideration of the instant paper, authorization is hereby given to charge the fee for the Appeal Brief and any necessary extension of time fees to Deposit Account No. 14-1447.

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I. REAL PARTY IN INTEREST

The real party in interest in this appeal is Novo Nordisk A/S, of Bagsvaerd, Denmark. The assignment was recorded in the U.S. Patent and Trademark Office on February 27, 2004 at REEL 015009, FRAME 0139.

II. RELATED APPEALS AND INTERFERENCES

Appellants, Appellants' representative or the Assignee are not aware of any other prior and pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claim 1 is pending. Claim 1 stand finally rejected. Thus, finally rejected claim 1 is at issue in the instant appeal and form the subject matter of the instant Appeal Brief and the cancelled claims do not stand or fall together. The claim in issue is attached in the "Claims Appendix". Applicants note that all claims other than claim 1 have recently been cancelled to simplify issues on appeal.

IV. STATUS OF AMENDMENTS

An Amendment under 37 C.F.R. § 41.33(b)(1) is filed concurrently herewith, which cancels claims 2-16 without prejudice or disclaimer, to simplify issues for appeal. Accordingly, the claim presented for appeal is that which is filed in the Amendment under

37 C.F.R. § 41.33(b) (1) filed concurrently herewith.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A. Claim 1

Independent claim 1 is drawn to a drug delivery system that comprises two separate devices: a drug delivery device (101) and an indicating device (102). The drug delivery device comprises a reservoir (111) that contains a drug and a means for delivering the drug into a body of a user in accordance with a delivery rate or profile. The means for delivering the drug is, for example, a pump. (*See* page 9, lines 20-251). The drug delivery device also comprises a processor means, which may be in the form of a processor (121) (*see id.)* and a first transmission means, such as an RF transmitter (*see* page 3, lines 30-35). The first processor means and transmitter means send data to a receiving means in the indicating device.

The second part of the drug delivery system is an indicating device that comprises a receiving means, such as receiver (*see* page 9, line 31) and a second processor means, such as a second processor (*see id.*). The receiving means and second processor means cooperate together to receive the data sent from the drug delivery device. The indicating device also comprises a timer means, such as a quartz controlled clock device (*see* page 10, lines 1-2). In addition, the indicating device comprises a memory means, such as an IC or a ROM (*see id.* at lines 3-5). A second processor means, such as a second processor (*see* page 9, line 31), is configured for calculating a time-dependent estimate of the amount of drug in the reservoir based upon data information and time information from the timer

1 All reference are to pages of the specification unless otherwise noted.

means. An indicating means (112), such as a monitor (*see* page 4, line 7), displays the calculated value.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The broad issues under consideration are:

1. Whether claim 1 is properly rejected under 35 U.S.C. § 103 as obvious over Ellinwood (US4146029), in view of Neftel (US 5764159) in view of Martinez *US 6592519) in further view of Applicants own Admission (AOA)

VII. ARGUMENTS

A. Summary of Rejections of Record

1. With regard to claim 1 the Examiner rejected claim 1 under 35 U.S.C. § 103 as being obvious under Ellinwood in view of Neftel , in view of Martize and in further view of Applicant's Own Admission (AOA). In particular, the Examiner asserts that Ellinwood discloses the reservoir and drug delivery means, that Neftel discloses the memory means and timer means, that Martinez discloses a second processor means that calculates a time-dependent estimate of drug in the reservoir, and that AOA shows a transmission means for transmitting data from the first processor to a receiving means. According to the Examiner it would have been obvious at the time of the invention to add the features of Martinez (i.e., remote monitoring) into Ellinwood/Neftel to provide a more effective system for remotely monitoring and controlling the amount of medication administered to a patient from a particular medical instrument. (*See* Final Rejection at page 5).

B. Citation of Authority

"Section 103 forbids issuance of a patent when the 'differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains.'" *KSR Int'l. Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1734 (2007). KSR reaffirms the analytical framework set out in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), which mandates that an objective obviousness analysis includes: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; and (3) resolving the level of ordinary skill in the pertinent art. *KSR*, 127 S. Ct. at 1734. Secondary considerations such as commercial success, long felt but unsolved needs, or failure of others "'might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.'" *Id.* (quoting *Graham*, 383 U.S. at 17-18.).

KSR states:

> Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.

KSR, 127 S. Ct. at 1740-41.

KSR further instructs "that when a patent claims a structure already known in the prior art that is altered by mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." *KSR*, 127 S. Ct. at 1740.

In expressly rejecting the "obvious to try" argument in support of patentability, *KSR* states:

> The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious by merely showing that the combination of elements

> was "obvious to try." ...When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

KSR, 127 S. Ct. at 1742.

To establish a *prima facie* case of obviousness under 35 U.S.C. § 103, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) and MPEP 2142. "If the Examiner fails to establish a *prima facie* case, the rejection is improper and will be overturned." In re Rijckaert, 9 F.3d, 1532, 28 U.S.P.Q.2d, 1956 (Fed. Cir. 1993), citing In re Fine, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988).

The appropriate starting point for a determination of obviousness is stated in Graham v. John Deere Co., 383 U.S. 1, 17, 148 U.S.P.Q. 459, 466 (1966):

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

The test of obviousness *vel non* is statutory and requires a comparison of the claimed subject matter as a whole with the prior art to which the subject matter pertains. In re Brouwer, 77 F.3d, 422, 37 U.S.P.Q. 2d 1663 (Fed. Cir. 1996); In re Ochiai, 71 F.3d 1565, 37 U.S.P.Q. 2d 1127 (Fed. Cir. 1995). Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. MPEP 2143.01.

C. Claim 1 Is Not Properly Rejected Under 35 U.S.C. § 103

As noted above, a rejection under 35 U.S.C. § 103 can only be maintained if there is a reason to modify the prior art to produce the claimed invention as a whole. And, importantly, a rejection under 103 cannot be maintained if the prior art references, when read together fail to teach or suggest all the claim limitations. This is exactly the case here.

While applicants do not necessarily agree with all of the Examiner's assertions and interpretations of the prior art in the Final Rejection of claim 1, in order to simplify issues for appeal, Applicants will, at this point, only raise the arguments with respect to the limitation that the second processor means in the indicating device calculate a time-dependent estimate for the amount of drug in the reservoir of the drug delivery device.

Indeed, one important aspect of the invention in claim 1 is that by having a

system that comprises two separate devices, the monitor or indicating device need not be constantly carried by the user or need not be in constant communication with the drug delivery device. Specifically, the present invention of claim 1 is based on the concept that desired information can be provided by estimating values based on known data. For example, a child who is using an infusion device for insulin delivery and is attending kindergarten in the morning might use such a system of claim 1. Just before the attending parent leaves the child, he gets the indicating device updated with the latest information from the drug delivery device. The parent is now able to follow the estimated amount of insulin or other drug left in the reservoir without being near the child and could get an alarm if the amount of insulin is too low. While a similar a feature could be realized by using mobile phone technology the cost of implementing actual monitoring and continuous two-way communication would be quite high. Thus, the present invention has considerable advantages. (*See* page 3, lines 20-35 and page 8 lines 6-14).

In the final rejection, the Examiner has asserted that Martinez discloses a "second processor means (122) adapted for calculating a time-dependent estimate for the amount of drug in the reservoir based upon received data information and time information from the timer means, and indication beans cooperating with the second processor means for indicating a calculated value." The Examiner cites to Martinez Column 7, lines 50-67. Applicants respectfully disagree with the Examiner's assertion and interpretation of Martinez.

A careful reading of the cited passage of Martinez reveals that the Examiner's statement is incorrect and that only the following is disclosed: a "[d]rug reservoir 100 can

contain a drug 101. Drug delivery catheter 110 can have a diamond or diamond-like coating 120, and a sensor 111 that can monitor the amount, chemistry and concentration of a drug 101 pumped by a pump 90 from reservoir 100 through the drug delivery catheter 110." Thus, the cited portion of Martinez reveals that that device monitors the actual amount of the drug. The Martinez device does not teach calculating a time-dependent estimate of the amount of drug remaining in the reservoir. There is clearly a difference between, on the one hand, monitoring remotely an actual quantity of drug in a reservoir and, on the other hand, calculating an estimate of the amount of drug in the reservoir. The Examiner has ignored this difference, and thus has misinterpreted the scope of the claim and the content of the prior art. The final rejection is therefore fatally flawed.

Applicant's note that there nothing to suggest modifying the prior art to calculate the time-dependent estimate, as is required by claim 1, and there is no indication whatsoever that one of ordinary skill would make such a modification to the prior art. Indeed, the Examiner has not pointed to single reason to modify the prior art to function in the manner required by claim 1. Nor has the Examiner cited any reference that teaches the calculating of an estimated value in a remote indicating device instead of a measured and transmitted value. Instead of addressing the limitation that the indicating device calculate a time-dependent estimate, the Examiner ignores this limitation entirely and instead substitutes the limitation that the indicating device monitors the amount of drug in the drug delivery device and then cites Martinez as having this new made-up limitation. (*See* Final Rejection at page 5). The Examiner then searches for and finds a reference that teaches this element, which is not an element required by the claim.

In short, claim 1 requires that the indicating device, which is a separate and distinct device from the drug delivery device, calculate a time dependent estimate of the amount of drug remaining in the reservoir and that this value is indicated to a user. The prior art does not show a separate indicating or remote device performing calculations to generate and display an estimated value of drug remaining in a separate drug delivery device.

VIII. CONCLUSION

Appellants respectfully submit that the Examiner has failed to make out a *prima facie* case of obviousness by failing to show how the prior art relied upon shows all the elements of the claim. In particular, the Examiner has read out of the claim the requirement that the indicating device calculates a time-dependent estimate of the amount of drug in the drug delivery device and read into the claim that the indicating device monitors the actual amount of drug in the drug delivery device. These are entirely different concepts. That the Examiner found prior art that shows remote monitoring cannot support a rejection of the claim, as the claim does not require remote monitoring; it requires calculating an estimate. Therefore, Applicants, respectfully request that the Board reverse the Examiner's decision to finally reject claim 1, and to allow the application to issue in its present form.

Respectfully submitted,

Date: May 19, 2009

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23650
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CLAIM(S) APPENDIX

1. A drug delivery system (100) comprising a delivery device (101) and an indicating device (102), the delivery device comprising:

- a reservoir (111) containing an amount of a liquid drug,
- means (111, 121) for delivering the drug into a body of a user in accordance with a delivery rate value or profile,
- first processor means (121), and
- first transmission means (131) cooperating with the first processor means for transmitting data information to receiving means in the indicating device,

the indicating device comprising:

- first receiving means (132) for receiving data information transmitted from the delivery device,
- memory means (124) for storing data information,
- timer means (123),
- second processor means (122) adapted for calculating a time-dependent estimate for the amount of drug in the reservoir based upon received data information and time information from the timer means, and
- indication means (112) cooperating with the second processor means for indicating a calculated value.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.